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10/689,359	10/20/2003	Natarajan Ranganathan	KBI-0015	4537

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/689,359	RANGANATHAN, NATARAJAN	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The applicant should note that the examiner in the case has changed.

The examiner notes the amendments to claims 1-3 and 7-11 and to the specification.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Priority

The examiner thanks the applicant for updating the status of the parent cases.

Claim Rejections - 35 USC § 112

The rejections of claims 2, 3, and 7 under 35 U.S.C. § 112, second paragraph, on the grounds detailed in the first Office action are withdrawn in light of the amendments to the claims.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 requires that the claimed composition comprise, in part, for example, "about 47% to about 82% of at least one carbohydrate ingredient", which is confusing. It is not clear whether the numbers are a comparison to the entire composition or to the carbohydrate ingredient. Clarification is required;the language of claim 8 is preferred. Because claims 2-7 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The rejections of claims 1-11 under 35 U.S.C. § 102(b) as being anticipated variously by U.S. Patents 5,902,578; 5,085,874; 5,744,134; and 5,518,740 are withdrawn in light of the amendments to the claims.

Double Patenting

Claim 10 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6.706,287. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim is to a a nutraceutical composition to alleviate symptoms of uremia, comprising a probitoic, prebiotic, and an amoniaphilic urea degrading microorganism with pH stability and urea degrading activity. The claim of the patent contains the above components with more additives. Therefore the instant composition encompasses the composition of the cited patent.

Applicant alleges that a terminal disclaimer in accordance with 37 C.F.R. § 1.321(c) was filed in this case, but none such document is in the case file. As such, the rejection stands.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,902,578 (Halpin-Dohnalek et al.). The claims are drawn to a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient. In some dependent claims, the probiotic bacteria is selected from a list; the product provides 5 – 20 billion CFUs; the carbohydrate is selected from a list; and the composition further comprises at least one vitamin and mineral.

Halpin-Dohnalek et al. teach a nutritional composition comprising protein, fat, carbohydrates and the probiotic bacteria *Lactobacillus reuteri, L. acidophilis* and *Bifidobacterium infantis* (abstract). The reference teaches that the composition is useful for maintaining GI health, and teaches a method for restoring GI health by administering the composition (abstract). Halpin-Dohnalek et al. additionally teach the compositions further comprising minerals and vitamins (col.3 line 30-50) as well as sucrose (claims). Halpin-Dohnalek et al. provide examples of the composition wherein the compositions provide $10x10^9 – 5x10^9$ (or 5 – 10 billion) CFUs of *L. reuteri* (example 1). Halpin-

Dohnalek et al. do not teach the specific amounts of each component recited in the current claims.

A person of ordinary skill in the art would have had a reasonable expectation of success in making the composition of Halpin-Dohnalek et al. with the recited amounts of each component because Halpin-Dohnalek et al. teach that the composition of their mixture may be varied (column 4, lines 1-28). The skilled artisan would have been motivated to vary the amounts of each component in order to optimize the nutritional value of the mixture for various individuals.

The selection of the amounts of each component clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Halpin-Dohnalek et al. teach that the amounts of each component may be varied. A holding of obviousness over the cited claims is therefore clearly required.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 1, 3-6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,085,874 (Jungvid). The claims are drawn to a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient. In some dependent claims, the carbohydrate, fat, and protein are each selected from a list. The composition further comprises at least one vitamin and mineral. Applicant additionally claims a nutritional food or product for maintaining or enhancing GI health, comprising

at least one carbohydrate, fat, protein, vitamin, mineral, prebiotic and probiotic, wherein the probiotic has a propensity to hydrolyze nitrogenous waste products and comprising about 2%-12% of at least one fat.

Jungvid teaches nutritional compositions comprising vegetable proteins, whey, vitamins, sodium caseinate, fat (lard, soy oil), animal proteins, starch (a prebiotic), dextrose (carbohydrate), minerals, probiotics (Lactobacillus bulgaricus, which hydrolyzes nitrogenous waste products) and lactulose (example 1). Jungvid does not teach the specific amounts of each component recited in the current claims.

A person of ordinary skill in the art would have had a reasonable expectation of success in making the composition of Jungvid with the recited amounts of each component because Jungvid teaches that the composition of the mixture may be varied (column 2, lines 23-33). The skilled artisan would have been motivated to vary the amounts of each component in order to optimize the nutritional value of the mixture for various individuals.

The selection of the amounts of each component clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Jungvid teaches that the amounts of each component may be varied. A holding of obviousness over the cited claims is therefore clearly required.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 1, 3-5, 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,744,134 (Paul). The claims are drawn to a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient. In some dependent claims, the carbohydrate, fat, and protein are each selected from a list. The composition may further comprise at least one prebiotic selected from a list Applicant finally claims a method for restoring and maintaining gastrointestinal (GI) health, comprising administering to a subject at least one food or nutritional product comprising an effective amount of probiotic bacteria and an effective amount of a prebiotic; and a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an ammoniaphilic urea-degrading microorganism with pH stability and urea degrading activity.

Paul teaches compositions for restoring and maintaining GI health, comprising immunogloblins (protein), FOS (prebiotic), pectin (prebiotic), *Lactobacillus* and *Bifidobacteria* (abstract). The immunoglobulin, or protein, is derived from milk or whey (abstract); and the bacteria may be *Lactobacillus acidophilis, L. bulgaricus, L. casei, L. fermentum, L. salivaroes, L. brevis,* or *L. plantarum,* or *Bifidobacterium adolescentis, B. infantis, B. longum, B. thermophilis,* or *B. bifidum* (col.4 line 20-29). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45).

Although Paul does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics. Paul also does not teach the specific amounts of each component recited in the current claims.

A person of ordinary skill in the art would have had a reasonable expectation of success in making the composition of Paul with the recited amounts of each component because Paul teaches that the composition of the mixture may be varied (column 4, lines 1-52; and column 13, line 47, through column 14, line 38). The skilled artisan would have been motivated to vary the amounts of each component in order to optimize the nutritional value of the mixture for various individuals.

The selection of the amounts of each component clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Paul teaches that the amounts of each component may be varied. A holding of obviousness over the cited claims is therefore clearly required.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 1, 3-5, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,518,740 (Costanzo et al.). The claims are drawn to a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein

ingredient. In some dependent claims, the carbohydrate, fat, and protein are each selected from a list. In some dependent claims, the composition further comprises a prebiotic selected from a list. Applicant further claims a nutraceutical composition to alleviate symptoms of uremia, comprising a probitoic, prebiotic, and an amoniaphilic urea-degrading microorganism with pH stability and urea degrading activity; and a yogurt or yogurt based product comprising at least one probiotic, carbohydrate and protein.

Costanzo et al. teach a yogurt composition (abstract) comprising *Lactobacillus bulgaricus* (probiotic), whole milk (milk proteins), dextrose (carbohydrate) and inulin (a prebiotic) (example 1). Costanzo et al. additionally teach the yogurts comprising *Lactobacillus bulgaricus*, whole milk (milk proteins), dextrose (carbohydrate), banana smash (prebiotic, or banana fiber), and soy lecithin (fat) (example 2). The compositions may alternatively comprise pectin (prebiotic) (example 3).

Although Costanzo et al. do not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics. Costanzo et al. also do not teach the specific amounts of each component recited in the current claims.

A person of ordinary skill in the art would have had a reasonable expectation of success in making the composition of Costanzo et al. with the recited amounts of each component because Costanzo et al. teach that the composition of the mixture may be varied (column 6, lines 50-59, and column 7, lines 20-32). The skilled artisan would

have been motivated to vary the amounts of each component in order to optimize the nutritional value of the mixture for various individuals.

The selection of the amounts of each component clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Costanzo et al. teach that the amounts of each component may be varied. A holding of obviousness over the cited claims is therefore clearly required.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

LEON B. LANKFORD, JR.
PRIMARY EXAMINER